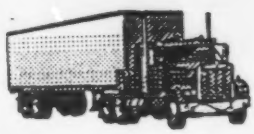
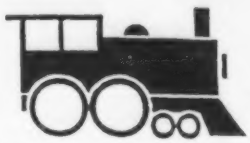
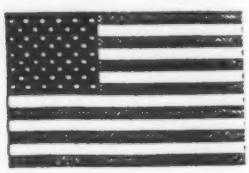




FDA

IMPORT ENTRY PROCEDURES FOR UPSTATE NY



IMPORTING FDA-REGULATED PRODUCTS INTO THE UNITED STATES

FDA/BUFFALO OFFICE/IMPORT OPERATIONS BRANCH

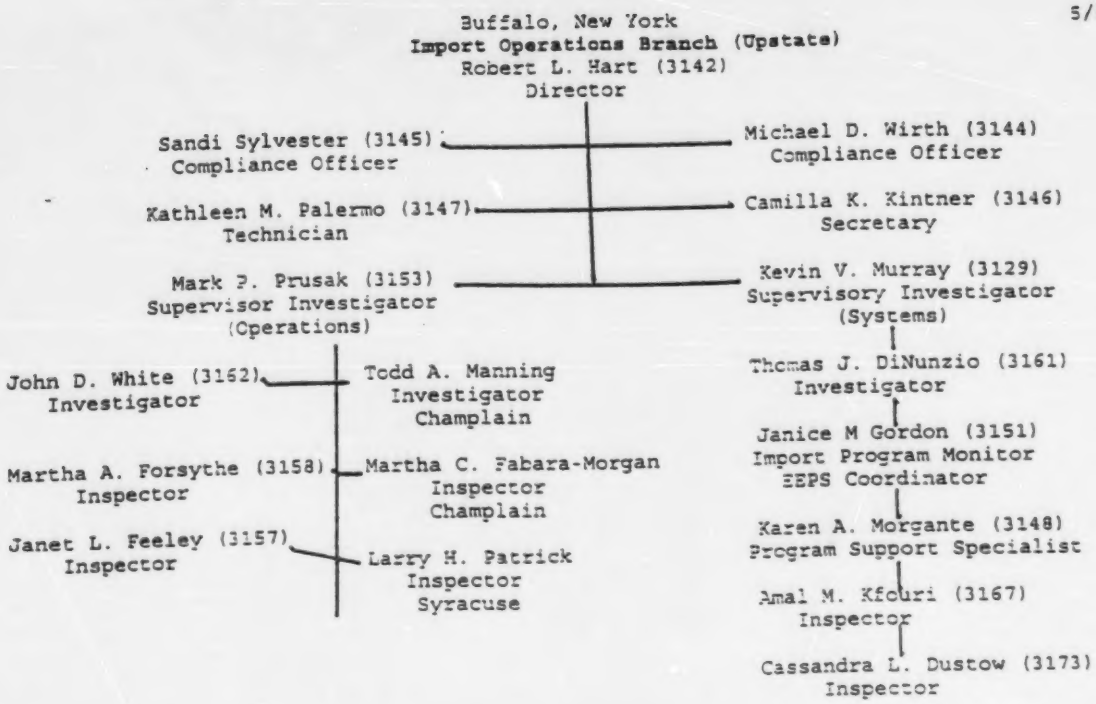
TABLE OF CONTENTS

I.	**IMPORT CONTACTS**	1.2	11/4/96
	- FDA/Buffalo District Import Operations Branch/Table of Organization	2	5/2/00
	- FDA DISTRICT Offices & Import Program Managers	3	5/1/00
	- Canadian Department of Foreign Affairs & International Trade (Mr. Neil Baisi)	4	10/31/96
	- FDA Reference for Regulatory or Technical Inquiries	5-6	10/31/96
II.	**MINIMIZING BORDER DELAYS**	**6.1**	**11/4/96**
	- Message for Canadian shippers who export product to U.S. subject to FDA oversight	7	10/7/98
	- Suggestions to Foreign Exporters & U.S. Importers to Expedite Entries	7.1	6/5/98
	- IMPORTS MINIMIZING BORDER DELAYS	8-9	10/31/96
	- What FDA looks for When Reviewing Import Entry Packets	10-11	10/31/96
III.	**THE PROCESS**	**11.1**	**11/4/96**
	- General Import Information	12.1-12.4	2/15/00
	- IMPORT PROCEDURE FLOW CHART	13	10/31/96
	- DOCUMENT EXAMINATION (flow chart)	14	10/31/96
	- DOCUMENT EXAMINATION ("bullets")	15	10/31/96
	- SHIPMENT EXAMINATION (flow chart)	17	10/31/96
	- FDA Examines Shipment (WHARF EXAMINATION)	18	10/31/96
	- PHYSICAL EXAMINATION	19	10/31/96
	- VIOLATION – PRODUCT DETAINED	20	10/31/96
	- RECONDITIONING/REFUSAL/BOND ACTION	21	10/31/96
	- RECONDITIONING PROCESS (flow chart)	22	10/31/96
	- REFUSAL PROCESS (flow chart)	23	10/31/96
	- MITIGATION OF LIQUIDATED DAMAGES	24	10/31/96
	- Automatic Detentions & Private Laboratory Analyses	25	10/31/96
	- Commercial Private Laboratories	26	1/30/01
IV.	**LABEL REVIEW**	**26.1**	**11/4/96**
	- FDA General Information & Label Review Procedures	27	10/31/96
	- "A FOOD LABELING GUIDE" order form	28	10/31/96
	- Why a Food Labeling Guide?	29	10/31/96
v.	**REFERENCES**	**29.1**	**11/4/96**
	- How to make a Freedom of Information Act Request to FDA	30.1-30.3	10/7/98
	- How to Obtain FDA Regulations	31.1-31.2	1/30/01
	- Welcome to Internet FDA	34.1-34.2	1/30/01
	- a. ORA Import Program Web Site	34.3	1/30/01
	- b. Food Safety Selected Highlights	34.4-34.5	1/30/01
	- Food Safety Selected Highlights	34.2	2/23/00
	- CFSAN Order Form for LACF Publications	35.1-35.2	1/30/01
	- Information for Companies Regulated by FDA	36.1-36.2	1/30/01
	- Importation of Animal Products	37	10/31/96

Import

Contacts

5/02/00



All personnel are assigned to Buffalo, unless otherwise indicated. Number in ( ) is the extension number.

Buffalo

The Buffalo Import Operation is located at: Olympic Towers
300 Pearl St., Suite 100
Buffalo, New York 14202.

Location	Telephone #	FAX #
Import Operations	716/551-4461	716/551-3813
Extended hours desk	716/551-4461, Ext 3149	716/551-5688
Help line	716/551-3839	
Peace Bridge	716/551-5941	716/688-2487
Lewiston Bridge	716/284-4169	716/282-0793.

U.S. Mail should be directed to the District Office at the above address. Express packages should be directed to: 179 Franklin Street
Buffalo, NY 14202.

Champlain

The Champlain import operation is located at: Route #87 Crossing
West Service Road behind USCS
Champlain, New York 12919

Mailing address: c/o US Customs
198 West Service Road
Champlain, New York 12919

Telephone: 518/298-8240 & 518/298-3295
FAX: 518/298-5538

Syracuse

The Syracuse import operation is located at: 250 S. Clinton St., Suite 120
Syracuse, New York 13202

Mailing address: PO Box 7197
Syracuse, New York 13261-7197

Telephone: 315/448-7601 & 315/448-7603
FAX: 315/448-7623

i:\docs\news\iobchart.doc

5/2/00

FDA District Offices

FDA District Offices throughout the United States can help you with import procedures (ask for an Import Branch Compliance representative).

Eastern States

MA, ME, NH, VT, RI, CT
One Montvale Ave.
Stoneham, MA 02180-3542
617/279-1675

NJ
Waterview Corp. Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
973/905-4205

GA, NC, SC
60 Eighth St., NE
Atlanta, GA 30309
404/253-1163

NY (Downstate)
158-15 Liberty Ave.
Jamaica, NY 11433
718/340-7000

PA, DE
U.S. Customhouse, Room 900
2nd & Chestnut Sts.
Philadelphia, PA 19106-2973
215/597-4390

FL
555 Winderley Place, Suite 200
Maitland, FL 32751
407/475-4700

NY (Upstate)
300 Pearl St., Suite 100
Buffalo, NY 14202
716/551-4461

MD, DC, VA, WV
900 Madison Ave.
Baltimore, MD 21201
410/962-3396

PR
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223
809/729-6844

Middle States

MI, IN
1560 East Jefferson Ave
Detroit, MI 48207
313/226-6260

OH, KY
6751 Steger Dr.
Cincinnati, OH 45237-3097
513/684-3501

LA, MS
4298 Elysian Fields Ave.
New Orleans, LA 70122
504/253-4500

MN, WI, ND, SD
240 Hennepin Ave.
Minneapolis MN 55401-1999
612/334-4100

KS, IA, NE, MO
11630 West 80th St
Lenexa KS 66285-5905
913/752-2413

TX, AR, OK
3310 Live Oak St.
Dallas, TX 75204
214/655-5315

IL
300 S. Riverside Plaza
Suite 550 South
Chicago, IL 60606
312/353-5863

TN, AL
297 Plus Park Blvd.
Nashville, TN 37217
615/781-5377

CO, WY, UT, NM
Bldg. 20, Denver Federal Center
P.O. Box 25087
Denver CO 80225-0087
303/236-3030

Western States

WA, OR, MT, ID, AK
22201 23rd Drive, SE
Bothel, WA 98021-4421
206/483-4952

CA (Northern), NV, HI
1431 Harbor Bay Parkway
Room 526
Alameda CA 94502-7070
510/337-6700

CA (Southern), AZ
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445
949/798-7601

In addition to the District Offices listed above, FDA Resident Inspection Posts are located in many major cities throughout the United States. To determine if a Resident Inspection Post is located in your city, consult the U.S. Government pages in the Government Listings (blue pages) section of the telephone directory under the listing: Health and Human Services
Dept. Of -----
Food and Drug Administration
(telephone # & address)

IMPORT PROGRAM MANAGERS

ATL-DO:	Vincent M. Williams	414/253-2240
BLT-DO:	Arthur T. (Ted) Ogdahl	410/631-0322, x16
CHI-DO:	Gerald J. Berg, Gurnee RP	847/249-8632, x22
CIN-DO:	Ronald H. Smith	513/679-2700, x162
DAL-DO:	L. B. Booty	214/655-5310, x337
DEN-DO:	William H. Sherer	303/236-3050
DET-DO:	Vickie L. Kaiser	313/226-5249
FLA-DO:	Jeanne Simmons	305/526-2800, x911
KAN-DO:	C. Richard Pendleton	913/752-2103
LOS-DO:	Irene Gomez	310/831-6123, x103
MIN-DO:	Catherine Levar	612/334-4100, x247
NOL-DO:	Tura L. King	504/253-4552
NSV-BR:	Denise D. Duncan	901/544-0345, x11
NWE-DO:	Frank J. Mazzoni	781/279-1675, x124
NYK-DO:	Alonza Cruse (Downstate)	718/340-7000, x5461
	Kevin Murray (Upstate)	716/551-4461, x3129
PHI-DO:	Alfred Puglia	215/597-4390, x4540
SAN-DO:	Janet Codor	510/337-6786
SEA-DO:	Kristy D. Thies	425/483-4951
STL-BR:	Sue Petru	314/645-1167, X152
SJN-DO:	Candido Torres	787/729X2176

Department of Foreign Affairs and International Trade
Ministère des Affaires étrangères et du Commerce international

Neil J. Baisi

United States Trade Relations Division
(UER)

125 Sussex Drive
Ottawa, Ontario
K1A 0G2
(613) 944-1015 Facsimile *(613)* 944-4840

Canada

10/31/96

...SAN-DO IOB Handout: References for Regulatory or Technical Inquiries

FDA References for Regulatory or Technical Inquiries

Send your specific questions to one of the units listed below.

Subject Area	Address	Telephone
All Foods (meat and poultry excluded), Food Additives, Colors for Food, Cosmetics (Note: no product label reviews accepted.)	Center For Food Safety & Applied Nutrition Division of Enforcement (HFS-605) 200 C Street, S.W. Washington, D.C. 20204	202-205-4187 202-205-0208 (Fax)
Drugs JOEL ARONSON NON-TERRITORIAL DRUG COMPLIANCE TERR. (HFD-310) 301-827-1367	Center for Drug Evaluation and Research Division of Drug Labeling Compliance (HFD-310) 7520 Standish Place Rockville, Md 20855	301-594-0063 301-594-0165 (Fax) Drug Listing 301-594-1086 301-594-1122 (Fax)
Medical Devices and Diagnostics TV's, Microwave Ovens, X-rays, Lasers, Ultrasound	Center for Devices and Radiological Health Div. of Compliance Operations (HFZ-320) 1390 Piccard Drive Rockville, MD 20850	800-638-2041 301-594-4598 301-594-4610 (Fax) Reg. & Listing 301-594-4699
Animal Drugs and Feed, Feed Additives, Animal Food	Center for Veterinary Medicine Division of Compliance (HFV-230) 7500 Standish Place Rockville, MD 20855	301-594-1726 301-594-1812 (Fax)
Biologics	Center for Biologics Evaluation and Research Office of Compliance (HFM-600) 1401 Rockville Pike Rockville, MD 20850	301-594-2006 301-594-0413 (Fax)
Imports	Div. of Import Operations (HFC-170) 15800 Crabbs Branch Way Rockville, MD 20855	301-443-6553 301-594-0413 (Fax)

Below are other numbers commonly requested. These offices do not provide label reviews

International Communications	International Affairs Staff (HFY-50) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	301-443-4480
General Import Information	Import Operations Branch (HFC-170) Food and Drug Administration	301-443-6553

Page 5

	5600 Fishers Lane Rockville, MD 20857	
Freedom of Information Inquiries	Freedom of Information Staff (HFI-35) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	301-443-6310
Consumer Publications & Audiovisuals	Consumer Info. & Outreach (HFE-88) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	301-443-5006

Minimizing

Border Delays

DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

About your Customshouse Broker -

Message for Canadian shippers who export product to U.S. subject to FDA oversight

The United States Food and Drug Administration (FDA) wishes to inform Canadian shippers who export products subject to its jurisdiction about a new electronic information filing system, named OASIS (Operation and Administrative System for Import Support). The system allows qualified customshouse brokers to file entry information with US Customs and the FDA electronically via computer. A National program evaluates the data, and the vast majority of the entries receive an electronic "may proceed" message which completes required interaction with the FDA. All brokers may qualify to participate in the program, but they must first prove they can accurately and consistently provide electronic information about each line item, which includes a product code, country of origin code, shipper, and manufacturer. When a broker first comes "on line," they are called a "dual mode" filer. While in this mode, they are required to submit both "paper" information, as well as "electronic" data for each entry. FDA compares the two, and when the broker consistently achieves a 90% accuracy rate, they are placed in a "paperless" mode. FDA encourages you to become informed about the OASIS status of the broker you utilize to enter your products into the US. Some have elected not to participate in the system until it becomes mandatory. Others have not yet mastered the system sufficiently to be placed into the paperless mode. Paperless brokers or filers can enter your product quickly and receive almost instantaneously information about the status of your product from FDA's perspective. In most cases, your customers can use or sell your product instead of holding the lot pending resolution from FDA.

SUGGESTIONS TO FOREIGN EXPORTERS & U.S. IMPORTERS TO EXPEDITE ENTRIES

Be sure packaged foods, drugs, devices, and cosmetics are fully labeled. Unlabeled or partially labeled goods must necessarily be detained because of lack of the mandatory label information. This causes delays that might not otherwise occur.

Do not import products known to be illegal on the theory that they can be brought into compliance with the law upon arrival. Conditional releases for that purpose are discretionary under the Federal Food, Drug, and Cosmetic Act and if the privilege is granted, delays and added expense to importers inevitably occur before final release or denial of release. Correct at the source obviously objectionable conditions responsible for detentions, such as infestation of crude drugs, foods, etc., with insects and other vermin.

Make U.S. Customs entries promptly upon arrival of shipments at the port of entry. The Food and Drug Administration cannot ordinarily act upon an importation until entry is actually filed and the Customs Service has notified the Agency's local office. Entry documents should be "flagged" for the attention of the FDA representative at the appropriate office.

To expedite handling of imported products, FDA is automating its import operations. By combining FDA's Operational and Administrative System for Import Support (OASIS) and Customs' Automated Commercial System (ACS), the FDA reviewer will be able to more efficiently evaluate and process each import entry. The import filer electronically transmits the required shipment-specific FDA data into the ACS via computer. Within several minutes, that individual receives notification that either their shipment has been released or FDA wishes to review it. In carrying on business transactions with the importing trade of the United States, foreign shippers, as well as the importing purchasers, should bear in mind that they have a definite obligation to comply fully with U.S. laws affecting these commodities. Sustained effort should be made to bring about fundamental correction of any existing conditions which adversely affect purity, strength, or quality of such articles.

Such corrective measures might well be undertaken by individual producers and associations of producers, and possibly by foreign government agencies in the countries of production. By such procedures, eradication of causes of deterioration and contamination in a number of commodities has already been successfully accomplished in various parts of the world, with a resulting great reduction in number of adverse actions by the Food and Drug Administration. Individuals, associations, and various foreign government agencies have, in a number of instances, instituted systems of sampling and examination of specific lots intended for shipment to the United States, for the purpose of predetermining whether they meet the requirements of the U.S. laws.

IMPORTS

MINIMIZING BORDER DELAYS

- MANDATORY LABEL INFORMATION
  - UNLABELED OR PARTIALLY LABELED GOODS WILL BE DETAINED BECAUSE OF LACK OF MANDATORY INFORMATION
- IMPORTATION OF KNOWN ILLEGAL PRODUCTS
  - ON THE PREMISE THEY CAN BE BROUGHT INTO COMPLIANCE
- PRODUCT HISTORY
  - KNOW THE PRODUCT'S ORIGIN, MANUFACTURING HISTORY, RAW MATERIAL PURITY, ETC.
- IMPORT/EXPORT PROCESS
  - SELECTION OF REPUTABLE CUSTOMS BROKER
  - FILING AN ENTRY - AVOID UNNECESSARY DELAYS
  - REPRESENTATION BY A CONSULTANT - CLEAR UNDERSTANDING OF RESPONSIBILITY

- COMPLIANCE WITH U.S. LAWS & REGULATIONS
  - KNOWLEDGE
  - CORRECTIVE ACTION
- COMMUNICATION
  - VITAL FOR ALL PARTIES IN THE IMPORTING PROCESS
- DOCUMENTATION
  -
  - INVOICE, B/L, ETC.
  - CORRESPONDENCE
  - REQUIRED INFORMATION - E.G. DEVICE LISTING REGISTRATION, PROCESS FILED, FDA 2877 (DECLARATION FOR PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS)

What FDA Looks For When Reviewing Import Entry Packets

All invoices should have adequate product names or descriptions in English such that FDA can determine whether it regulates the product or not. The manufacturer's name and address is to be identified for each product. Information regarding the shipping units and net weight of each unit or line item must be provided. The invoice must state if the products are being held under refrigerated/frozen conditions.

For specific products, FDA may look for FDA registration numbers, process numbers, etc., as follows:

Canned Foods

FCE Food Canning Establishment (FCE) Registration number - i.e., 01234

SID Low Acid Canned Food (LACF) or Acidified Low Acid Canned Food (ALACF) Process Submission Identifier (SID) number - i.e., 950105001
Size of can - diameter and height, i.e., 3" by 4 7/16" or 300x407

Ceramicware

CCC Chinese Commodity Inspection Branch (CCIB) original form pattern name or descriptive statement

Fresh and Frozen Shellfish

Interstate Certified Shellfish Shipper number - i.e., 5607 SS, or 79 SP

Soft Cheese

FCC French Cheese Plant Identification and Approval Number

Black Pepper

BPI Inspection Certificate For Export of Black Pepper

Seafoods

Acceptable Market Name or Common Name

Additives

AIN Food Additive Chemical Abstract System (CAS) Number, Flavor and Extract Manufacturers' Association (FEMA) number, or European Economic Community (EEC) number
i.e., CAS 302-72-7, EEC E415

FAP Food Additive Petition Approval Number

CIN Color Additive Number - i.e., AD-1234

Cosmetics

COS Cosmetic Registration Number (voluntary)

For specific products, FDA may look for FDA registration numbers, listing numbers, process numbers, etc., as follows:

Biologics

BFL Biological License number - i.e., 0123, 123-12, 123-123, 0123-12
Statement of investigational, non-human use per 21 CFR 312.160
Applicable drug or device registration, listing, etc., or exemption numbers

Drugs

DLS Drug Listing number - i.e., N-012345-C-0123
Note: the National Drug Code - i.e., NDC 0123-4567-89, is not the Drug Listing number
NDA New Drug Application (NDA) number - i.e., 20-123
AND Abbreviated New Drug Application (ANDA) number - i.e., 70-123
IND Exemption for an Investigation New Drug (IND) number - i.e., 40,123
Statement of investigational, non-human use per 21 CFR 312.160

Devices

DEV Medical Device Establishment Registration number of initial distributor -i.e., 2988888
Note: foreign firm registration numbers usually start with 80
LST Medical Device Listing number of specific product - i.e., A123456 or Q123456
PMN Premarket Notification [510(k)] number - i.e., K950123
Statement of pre-amendments status or exemption by regulation from 510(k)
PMA Premarket Approval (PMA) number - i.e., P950123
IDE Investigational Device Exemption (IDE) number - i.e., G950123
Statement of use in teaching, law enforcement, research & analysis per 21 CFR 801.125
IRC Impact Resistant Lens Certificate for non-prescription spectacle and lenses for sunglasses

Radiation-emitting electronic products

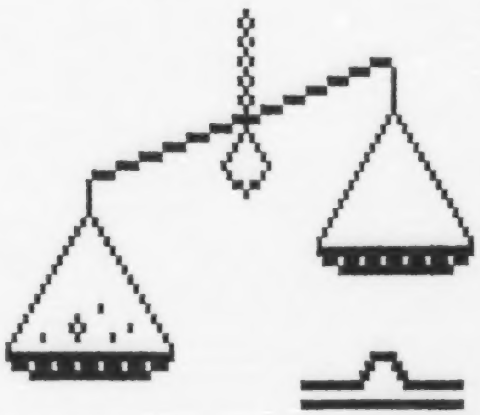
RA_ Declaration for Products Subject to Radiation Control Standards (FDA-2877), original
ACC Accession number - i.e., 9512345
Statement of exemption from performance standards

Veterinary Products

NAD New Animal Drug Application (NADA) number - i.e., 123-012-R8012
ANA Abbreviated New Animal Drug (ANADA) number - i.e., F123-345, G123-456
INA Investigational New Animal Drug number (INAD)- i.e., 8012/123-012, or 8001/1-drug-name
MFA Medicated Feed Application number - i.e., 123-456

10/31/96

The



Process

U.S. Food and Drug Administration

Import Information

Last Update: 17-MAR-1999 3:10 PM

UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
IMPORTS

The Food and Drug Administration (FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers' health, safety, and pocketbook. These laws apply equally to domestic and imported products.

With the exception of most meat and poultry, all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States. Most meat and poultry products are regulated by the U.S. Department of Agriculture.

All imported products are required to meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

As defined in the FD&C Act the term adulteration has to do with the content of a product (such as the addition of a substance which makes a product inferior, impure, not genuine, etc.) while misbranding includes statements on labels or labeling that are false or misleading.

FDA's IMPORT PROGRAM / GENERAL PROCEDURES

To ensure that FDA is notified of all regulated products imported into the United States, the importer, or his/her representative, must file an entry notice and an entry bond with the U.S. Customs Service (Customs) pending a decision regarding the admissibility of the product. FDA inspection and enforcement procedures for imports rely on coordination with Customs with whom FDA has an excellent working relationship. For specific information on U.S. Customs procedures, requirements, forms, etc., contact your local Customs office.

FDA is notified by Customs of the entry and makes a decision as to the article's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into United States commerce.

Generally, if FDA decides to examine an entry, an FDA representative will collect a sample from the shipment for laboratory evaluation. If the analysis indicates the product is in compliance, the shipment may be released into United States commerce. If there is a violation, the product will be refused admission. The FD&C Act, Section 801, directs FDA to refuse admission of any article that appears to be in violation of the Act.

When a sample of an article offered for import has been requested by FDA, the owner or consignee shall hold the shipment and not distribute it until further notice is received regarding the results of the examination of the sample. If it appears that the article is violative, FDA issues a Notice of Detention and Hearing to the owner or consignee of the article specifying a place and period of time whereby the individual may introduce testimony either verbally or in writing.

The importer is provided an opportunity to submit a petition to recondition the product to bring it into compliance. The owner or consignee may submit an application to FDA to relabel or perform other actions to bring the article into compliance or render the article other than a food, drug, device, or cosmetic. An application for authorization to relabel or perform other actions to bring the article into compliance shall contain a detailed proposal and specify the time and place where such operations will be carried out and the approximate time for completion as specified by regulation. All petitions to recondition a product are subject to FDA review and approval.

If the product is refused, the importer is required to either re-export or destroy the article under U.S. Customs or other approved supervision. If the refused product is not destroyed or re-exported, Customs issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in Customs assessing liquidated damages against the importer's bond.

DETENTION WITHOUT PHYSICAL EXAMINATION

In some instances a product may be detained as soon as it is offered for entry into the United States. This procedure is the administrative act of detaining a product without physical examination and is based on past history and/or other information indicating the product may be violative. A product may be subject to a detention without physical examination (DWPE) recommendation until the shipper or importer proves that the product meets FDA guidelines or standards.

Occasionally, FDA identifies products from an entire country or geographic region for DWPE when the violative conditions appear to be geographically widespread. Detention recommendations of this breadth are rare and are initiated only after other avenues for resolving the problem have been exhausted. (See FDA Regulatory Procedures Manual (RPM), Chapter 9-25-00 for details on Detention Without Physical Examination - formerly known as Automatic Detention).

IMPORT ALERTS

Import Alerts have been developed to communicate guidance to FDA field offices. The purpose of an Import Alert is to identify and disseminate import information (problems, violative trends, etc.) to FDA personnel thus providing for more uniform and effective import coverage. Import Alerts identify problem commodities and/or shippers and provide guidance for import coverage. They will identify products or shippers that have met the criteria for DWPE (see RPM, Chapter 9-25-00). For additional information or questions regarding DWPE, import alerts or import bulletins policy contact the Division of Import Operations and Policy (DIOP), HFC-170, 5600 Fisher Lane, Rockville, MD 20857.

COMPUTERIZATION

To assure the expeditious handling of imported products, FDA has automated its import operations. By combining FDA's Operational and Administrative System for Import Support (OASIS) and Customs' Automated Commercial System (ACS), an FDA reviewer will be able to more efficiently evaluate and process each import entry. The import filer transmits the required shipment-specific FDA data into the ACS. Within several minutes, the filer receives notification that either their shipment has been released or FDA wishes to review it. This system provides FDA with immediate data on imported products, provides information on potential problems, and maintains national historical data files to develop

profiles on specific products, shippers, and manufacturers. Eventually all filers processing entries through Customs' ACS will provide FDA information electronically.

FOREIGN TRADE ZONES

A foreign trade zone (FTZ) is an area in the United States designated by Customs to hold or otherwise manipulate goods for an unlimited period of time awaiting a favorable market in the United States or nearby countries without being subject to Customs entry, payment of duty, tax, or bond. These areas are considered outside the Customs territory of the United States for Customs importing procedures.

However, the location of an establishment in a foreign trade zone has absolutely no bearing on the jurisdiction or the applicability of the laws administered by FDA. Foreign trade zones are part of the United States and the movement of regulated products into or out of such zones, including export, constitutes interstate commerce. Therefore, regulated products in foreign trade zones must comply with those laws that come within the purview of the FDA.

ADDITIONAL FORMS

In addition to required entry forms, certain products require specific information to be presented to FDA at time of importation:
Foreign firms must register and file processing information before shipping any low-acid canned food or acidified low-acid canned food to the United States. This information must be provided to FDA for each applicable product at the time of importation in order to assure compliance with registration and process filing acceptance. Establishment registration (FDA 2541) and process filing forms (FDA 2541a - Food Process Filing For All Methods Except Low-Acid Aseptic; FDA 2541c - Food Process Filing for Low-Acid Aseptic Systems) can be obtained from the LACF Registration Coordinator, (HFS-618), Regulatory Food Processing and Technology Branch, Division of HACCP Programs, Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204.

The Federal Import Milk Act requires a permit for milk and cream (including sweetened condensed milk) imported into the United States. Information regarding how to obtain a permit is discussed in the Import Milk Act, 21 USC 141-149. This data, together with the permit request should be directed to the Food and Drug Administration, Regulations and Enforcement Branch, Division of Program and Enforcement Policy (HFS-306), 200 C Street SW, Washington, DC 20204.

Although it is not a requirement for foreign drug firms to register their establishments, their products must be listed with the FDA. Forms required to obtain a labeler code (FD 2656) and drug list their product (FD 2657) should be requested from the Center for Drug Evaluation and Research, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.

Drugs are restricted from importation unless they are covered under an Investigational New Drug Exemption (IND) or by an approved New Drug Application (NDA). Information on regulations covering INDs or NDAs and application forms should be requested from CDER Executive Secretariat (HFD-8), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857.

There are several forms that are required to be filed with FDA prior to the importation of medical devices into the United States.

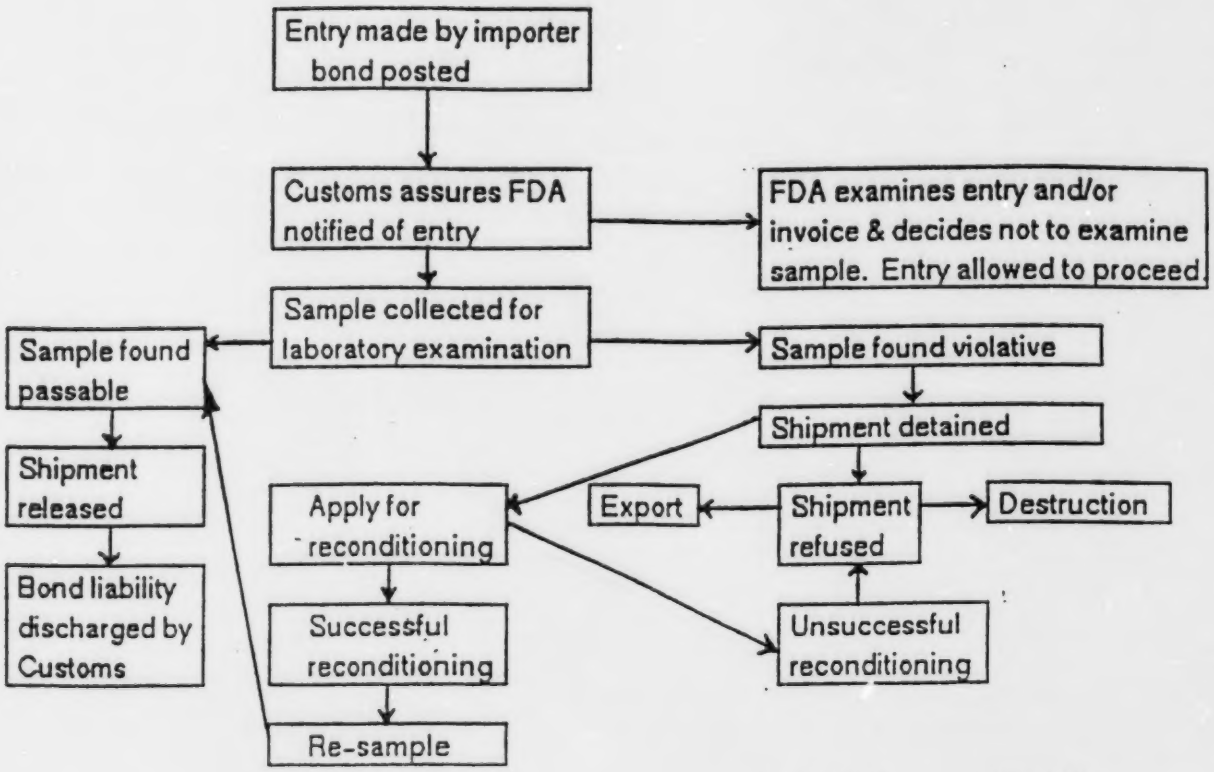
A premarket notification or 510(k) submission is required when the following occurs: (a) a foreign manufacturer intends to export a medical device to the U.S. that the firm has never before shipped to the U.S.; (b) either the foreign manufacturer or initial distributor changes the intended uses of devices that are legally being marketed in the U.S.; or (c) changes or modifications to a legally marketed device that could significantly affect its safety or effectiveness. Detailed information regarding the premarket notification process can be obtained from the following documents: Premarket Notification:

510(k), Regulatory Requirements for Marketing a Device, and 510(k) Review Program.

Firms are required to submit a properly completed form FDA 2892 (Medical Device Listing) before their medical device can be imported into the United States. Although, it is not a requirement for foreign medical device firms to register their establishments, it is requested that they do so. This can be done by submitting a properly completed form FDA 2891 (Initial Registration of Medical Device Establishment). Form FDA 2877 (Declaration for Radiation Standard) is required for radiation-emitting electronic products entering the United States.

To obtain these above forms, or information concerning premarket notification, radiation control standards, or Drug and Device Listing and Establishment Registration contact the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, (HFZ-220), 5600 Fishers Lane, Rockville, MD 20857, (800) 638-2041).

IMPORT PROCEDURE FLOW CHART



FLOWCHAR.WK1 Rev. 1/90

DOCUMENT EXAMINATION

IMPORTER FILES ENTRY NOTICE AND BOND WITH U.S. CUSTOMS

↓

FDA NOTIFIED OF ENTRY

↓

FDA REVIEWS IMPORTER'S ENTRY NOTICE

↓

A. REVIEW OF DOCUMENTATION PRESENTED

B. EVALUATE ADHERENCE TO AGENCY POLICIES AND PROGRAMS

C. DETERMINE DOCUMENTARY COMPLIANCE

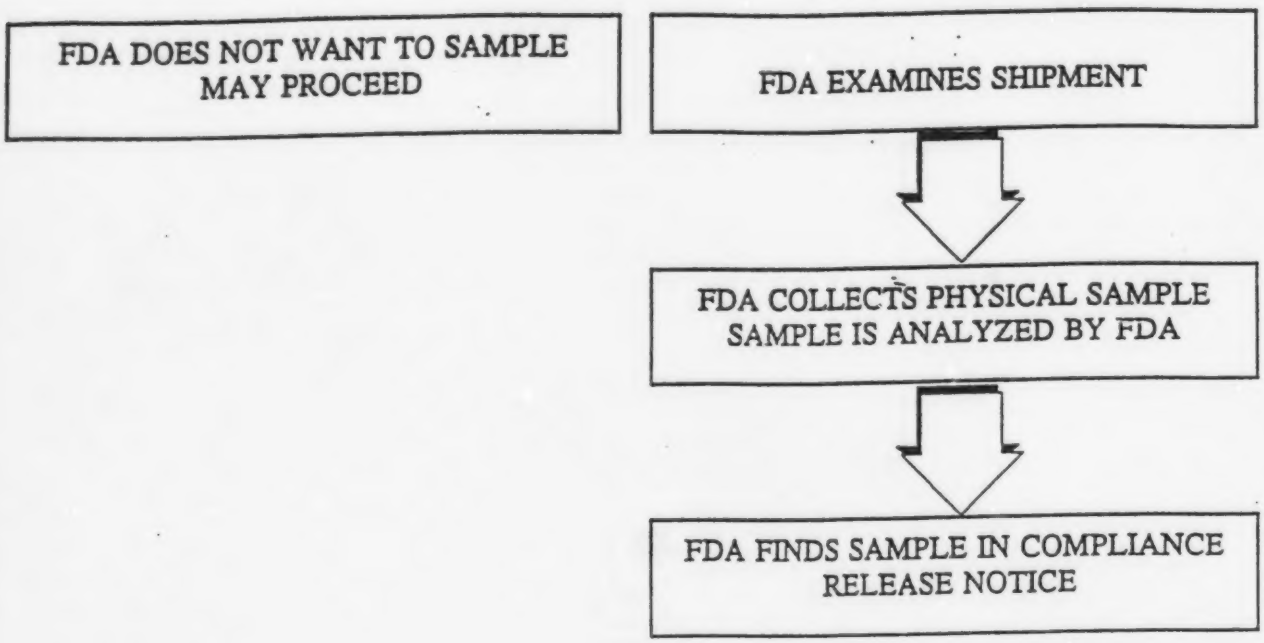
DOCUMENT EXAMINATION

FDA REVIEW OF IMPORTER'S ENTRY NOTICE

REQUESTED INFORMATION

- ENTRY NUMBER/DATE
- PORT OF LADING
- COUNTRY OF ORIGIN FOR PRODUCT
- PORT OF UNLOADING/ENTRY
- PORT OF ENTRY
- VALUE OF ENTRY
- IMPORTING VESSEL
- DATE OF ARRIVAL
- NAME/ADDRESS OF CONSIGNEE (IF DIFFERENT)
- NAME/ADDRESS OF IMPORTER OF RECORD
- NAME/ADDRESS OF FOREIGN MFR/SHPR
- BROKER
- LOCATION OF LOT
- DATE AVAILABLE
- GENERAL DESCRIPTION OF SHIPMENT
  (TOTAL QUANTITY, PACKAGED TYPE, ITEM,
  INVOICE MUST CONTAIN FULL DESCRIPTION)

SHIPMENT EXAMINATION



FDA EXAMINES SHIPMENT

WHARF EXAMINATION

- VISUAL PROBLEMS
  - GROSS FILTH-
    - LIVE/DEAD INSECTS
    - ABNORMAL CONTAINERS
    - ANIMAL FILTH
    - MOLDY PRODUCT/OFF ODOR

- LABELING CONCERNS-
  - ENGLISH REQUIRED INFORMATION
  - MEDICAL CLAIMS, RX PRODUCT

- PRODUCT CERTIFICATION
  - RADIOLOGICAL HEALTH (TV, MICROWAVE OVEN, X-RAY EQUIPMENT, SUN TANNING BEDS, ETC.)
  - MEDICAL DEVICE - LENS (IMPACT RESISTANT)
  - FOODS - GOVERNMENT CERTIFICATES

PHYSICAL EXAMINATION

- SANITATION -
  FILTH, INSECT, ANIMAL, BIRD, OTHER VERMIN, FOREIGN MATERIAL, DECOMPOSITION

- MICROBIOLOGICAL -
  PATHOGENS, BOTULISM, LISTERIA, SALMONELLA, CHOLERA

- METALS -
  LEAD, CADMIUM, MERCURY

- PESTICIDE RESIDUES

- PRODUCT STANDARDS

- POTENCY

VIOLATION - PRODUCT DETAINED

PROCEDURES TO BE FOLLOWED FOR DETENTION

RESPONSE TO NOTICE OF DETENTION AND HEARING

- APPEAL DETENTION
  - PROVE PRODUCT COMPLIES WITH LAW

- PETITION FOR RECONDITIONING/ RELABELING
  - FDA-766 APPLICATION

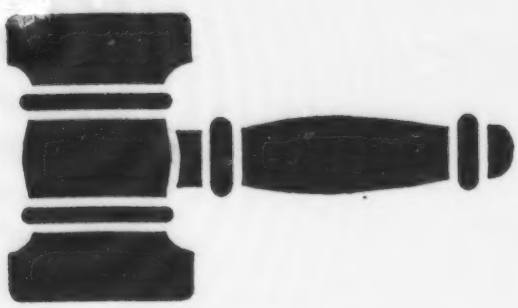
- PRIVATE LABORATORY TESTING
  - MUST MEET FDA GUIDELINES

- REJECT PRODUCT
  - RE-EXPORT
  - DESTORY
    (a) US CUSTOMS SUPERVISION
    (b) FDA SUPERVISION

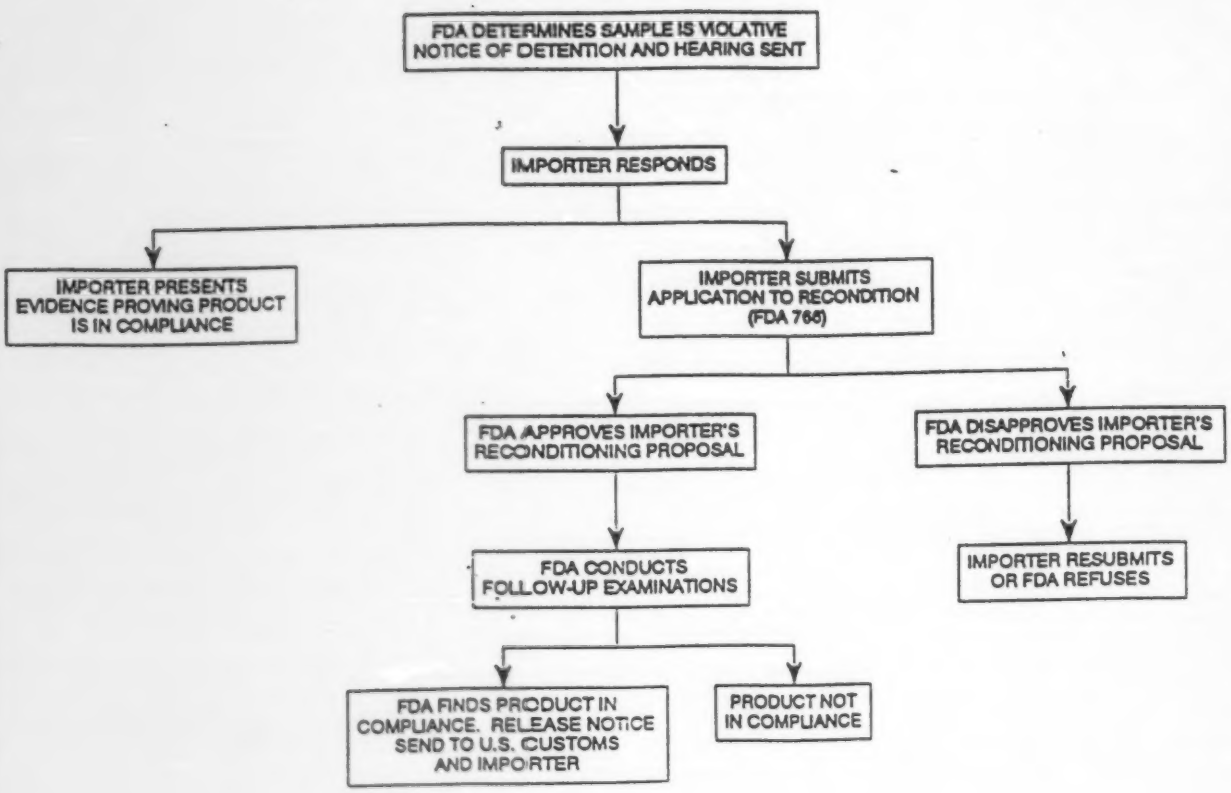
RECONDITIONING

REFUSAL

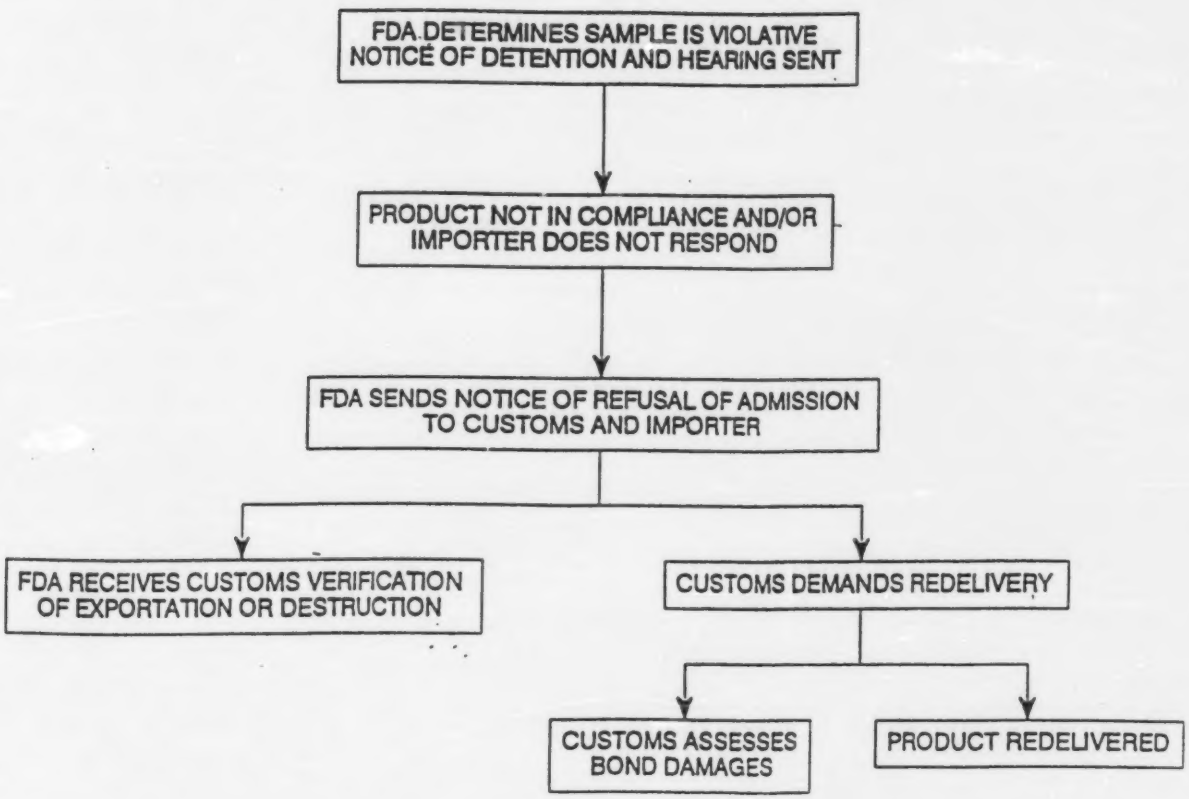
BOND ACTION



RECONDITIONING PROCESS


FDA DETERMINES SAMPLE IS VIOLATIVE NOTICE OF DETENTION AND HEARING SENT
IMPORTER RESPONDS
IMPORTER PRESENTS EVIDENCE PROVING PRODUCT IS IN COMPLIANCE
IMPORTER SUBMITS APPLICATION TO RECONDITION (FDA 766)
FDA APPROVES IMPORTER'S RECONDITIONING PROPOSAL
FDA DISAPPROVES IMPORTER'S RECONDITIONING PROPOSAL
FDA CONDUCTS FOLLOW-UP EXAMINATIONS
IMPORTER RESUBMITS OR FDA REFUSES
FDA FINDS PRODUCT IN COMPLIANCE. RELEASE NOTICE SEND TO U.S. CUSTOMS AND IMPORTER
PRODUCT NOT IN COMPLIANCE

REFUSAL PROCESS


FDA DETERMINES SAMPLE IS VIOLATIVE
NOTICE OF DETENTION AND HEARING SENT
PRODUCT NOT IN COMPLIANCE AND/OR
IMPORTER DOES NOT RESPOND
FDA SENDS NOTICE OF REFUSAL OF ADMISSION
TO CUSTOMS AND IMPORTER
FDA RECEIVES CUSTOMS VERIFICATION
OF EXPORTATION OR DESTRUCTION
CUSTOMS DEMANDS REDELIVERY
CUSTOMS ASSESSES
BOND DAMAGES
PRODUCT REDELIVERED

MITIGATION OF LIQUIDATED DAMAGES

PETITION TO U.S. CUSTOMS-

- CUSTOMS CAN MITIGATE ONLY WITH FDA AGREEMENT

FDA MITIGATION - CONSIDERATION DUE TO

- ACT OF GOD - BEYOND CONTROL OF IMPORTER
- FIRST TIME IMPORTER OF FDA PRODUCTS

Automatic Detentions and Private Laboratory Analyses

FDA has developed a procedure whereby some products are automatically detained when they enter the U.S. This procedure is an administrative act of detaining a product without physical examination and is generally based on past history and other information indicating the product may be violative. Once a product is placed on automatic detention, normal entry many not resume until the shipper or importer proves that the product meets FDA standards. Automatic detention action effectively takes FDA out of the quality control laboratory business and properly places the responsibility for determining quality and compliance with the law on an importer or broker. For removal from automatic detention see Criteria for Removal from Automatic Detention.

FDA considers automatic detention based on high violation rates for a single product or group of products, documented history of violative practices resulting in an FDA Warning letter without adequate response or correction, and information indicating misdeclaration to avoid FDA review or automatic detention. In some cases, recommendations for automatic detention may be based on one violative sample, i.e, condoms, examination gloves, actionable pesticide residue levels, etc. Our Division of Import Operations & Policy (DIOP) serves as the central repository for all automatic detention information and data.

Once placed on automatic detention, future entries of the same product will be automatically detained. The importer or broker has 10 working days from the date of detention to present evidence as to why their product should not be refused admission. Short extensions of the detention period may be requested, in writing, for submitting evidence.

For products which require relabeling or cleaning, a proposal is to be submitted on an FDA 766 form, Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts (FDA 766).

For products for which a private laboratory analysis is required for evidence of compliance, an FDA 766 is not required. Moreover, importers have a right to have a private laboratory draw samples and conduct analyses in order to respond to a Notice of Detention and Hearing. In some cases a detention will cover an entire entry. Importers are free to request extensions, in writing, of the detention period to allow for private laboratory sampling and analysis, to attempt to establish that the violation does not extend to all the items in the entry. FDA is prepared to grant reasonable extensions (usually 30 calendar days or less); but it is the importer's responsibility to request an extension before the deadline (and before any extended deadline). Once a refusal notice has issued, FDA will retract it only under very special circumstances; see information on Petitions for Rescinding an FDA Refusal Notice.

The importer and the private laboratory bear the entire responsibility for choosing appropriate methods of sampling and analysis. FDA will not 'approve' sampling and analytical procedures in advance. In general, private laboratories should follow accepted scientific standards of operation; see the Pacific Region Private Laboratory Guidelines. Each submission for private analytical results will be evaluated on its own merits. Integrity and scope of sampling are vitally important. Samples must be collected by a representative of the analyzing laboratory. As always, FDA reserves the right to collect audit samples, and examine the facilities and procedures of the private laboratory. No analytical results will be considered from laboratories which refuse to cooperate with such examinations.

The collection of private samples can result in shortages, in the event an entry must ultimately be redelivered for export or destruction. To forestall problems with U.S. Customs Service, importers and private laboratories should carefully document all sample collections.

...SAN-DO IOB Handout: Commercial Private Laboratories

Commercial Private Laboratories

FDA is unable to recommend commercial laboratories which conduct analyses on products which are under detention. Importers have the right to have a private laboratory draw samples and conduct analyses in order to respond to a Notice of Detention and Hearing whether the detention was automatic, or was based upon FDA analysis. If the product is being detained for failing defect action level (DAL) criteria, the product may be subject to referee sampling; see Detained Imported Foods Subject to Defect Actions Levels. If the detention is not due to failure of DAL criteria, then FDA's analysis for the violative product will take precedence over the private analysis.

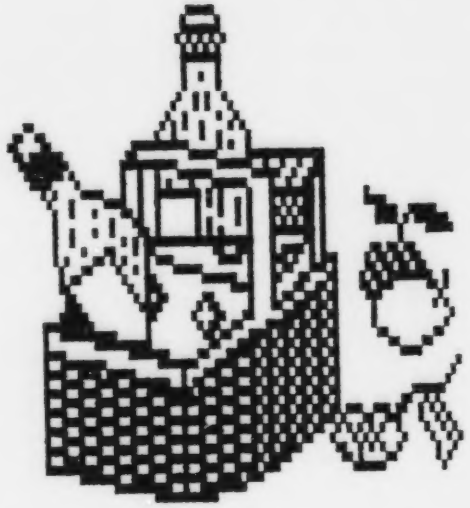
Listed below are three organizations that maintain lists of private laboratories. This information is provided only to aid the regulated industry in identifying private laboratories which may analyze import samples from entries which are under detention. We do not imply that the laboratories on these lists are "approved" or "certified" by FDA. It is the responsibility of the importer to assure that the laboratory is qualified and conducts the appropriate analysis.

American Council of Independent Laboratories, Inc.
1629 K Street
Washington, DC 20006
Phone: 202-887-5872
FAX: 202-887-0021
www.acil.org

ASTM Directory of Testing Laboratories
1916 Race Street
Philadelphia, PA 19103-1187
Phone: 215-299-5400
FAX: 215-977-9679
www.astm.org/labs

"Food Processors' Resource"
Food Processing
Putnan Publishing Company
301 E. Erie Street
Chicago, IL 60611
Phone: 312-644-2020
FAX: 312-644-1131
www.foodprocessing.com

Label



Review

FDA General Information and Label Review Procedures

The responsibility for compliance with FDA's regulations is on the manufacturers, importers and distributors themselves, and not the FDA. It is your responsibility to read the reference material for guidance on FDA. For labeling requirements, it is up to you to develop a final label. It is suggested that you consider contacting a private consultant such as an attorney, customs broker, printer, or Food & Drug related service organization for help on preparing your labels. Neither the FDA Small Business Representative nor personnel in other FDA offices are available to design your labels, act as technical consultants for you or recommend consultants. We suggest that you consult the Yellow Pages (i.e. Food and Beverage Consultants, Food Facilities Consultants Food Processing Consultants, Customs Brokers, etc.) or local associations for references.

LABEL REVIEW

Labels you are creating or changing should meet the rules in the appropriate commodity sections of the Code of Federal Regulations. Remember that it is your responsibility for correct product labels. FDA does not provide a label service.

WHAT FDA NORMALLY LOOKS FOR

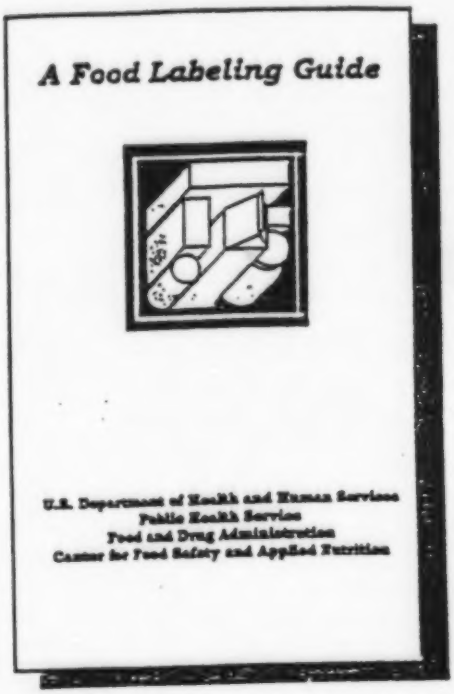
FDA samples imported shipments for our own purposes. We do not analyze products for the importer. If you want your product analyzed, look in the Business Yellow Pages under Chemists and Laboratories. The types of examinations that FDA normally performs are for filth, color additives, unsafe food additives, bacteria, poisonous and toxic substances (aflatoxin, lead, mercury, pesticides), purity and strength of drugs, sterility, short weight or fill, and labeling requirements. FDA cannot recommend specific private laboratories to you.

Food and Drug Administration's *recently released guide for the labeling of food products now contains the requirements of the Nutrition Labeling and Education Act, as well as Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act*

This 65 page booklet containing numerous illustrations, is a summary of the required statements that must appear on labels of foods produced in the United States, as well as food imported into tbe U.S.

Written in a easy to follow question and answer format with a key word index, the reader's area of concern can quickly be found, and the legal requirements easily understood.

Available from the Government Printing Office.


A Food Labeling Guide
U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Superintendent of Documents Order Form

Order Processing Code:
* 7539

Charge your order. It's easy!

To fax your orders (202) 512-2250
To phone your orders (202) 512-1800

☐ YES, send me ___ copies of A Food Labeling Guide, S/N 017-012-00370-2 for $4.50 each ($5.63 foreign).

The total cost of my order is $ _____. Price includes regular shipping and handling and is subject to change.

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, Zip code

Daytime phone including area code

Purchase order number (optional)

Check method of payment:
☐ Check payable to Superintendent of Documents
☐ GPO Deposit Account ☐
☐ VISA ☐ MasterCard

☐☐☐☐ (expiration date) *Thank you for your order!*

Authorizing signature

Mail To: Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250-7954

Why a Food Labeling Guide?

The Food and Drug Administration (FDA) is responsible for assuring that foods sold in the United States are safe, wholesome and properly labeled. This applies to foods produced domestically, as well as foods from foreign countries. The Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act are the Federal laws governing food products under FDA's jurisdiction.

The FDA receives many questions from manufacturers, distributors, and importers about the proper labeling of their food products. This booklet is a summary of the required statements that must appear on food labels under these laws and their regulations. To help minimize legal action and delays, it is recommended that manufacturers and importers become fully informed about the applicable laws and regulations before offering foods for distribution in the United States.

The Nutrition Labeling and Education Act, which amended the FD&C Act requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. Although final regulations have been established and are reflected in this booklet, regulations are frequently changed. It is the responsibility of the food industry to remain current with the legal requirements for food labeling. All new regulations are published in the Federal Register prior to their effective date and compiled annually in Title 21 of the Code of Federal Regulations.

In a booklet such as this, it is impractical to attempt to answer every food labeling question that might arise. The most frequently raised questions have been addressed using a "question and answer" format. We believe the vast majority of food labeling questions are answered. They are grouped by the food labeling feature of concern. The Table of Contents will help you locate your food labeling area of interest. The "Key Word Index" will also be helpful in locating specific food labeling concerns.

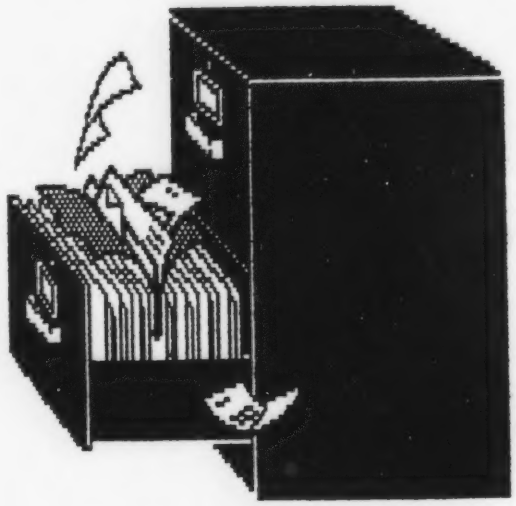
Under FDA's laws and regulations, there is no label approval necessary prior to the food products' distribution or importation. Questions concerning the labeling of food products may be directed to:

Division of Programs and Enforcement Policy (HFS-155)
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204
Telephone (202) 205-5229

Available from the Industry Activities Staff is the booklet " Food Labeling - Questions and Answers." It is an invaluable companion to this "Food Labeling Guide" and was developed specifically to address, in detail, the Nutrition Labeling and Education Act requirements.

The regulation numbers referenced for each question in this booklet identify FDA regulations in Title 21, Code of Federal Regulations (CFR). Information on ordering FDA's regulations and other food labeling publications appears on page 65 of this booklet.

References



Page 30.1
10/7/98

U.S. Food and Drug Administration

A Handbook for Requesting Information and Records from FDA

March 28, 1997

The guidance given in this handbook is intended to facilitate requests for both public information and records not originally prepared for distribution by FDA. This handbook has been updated in response to the Electronic Freedom of Information Act Amendments of 1996.

Obtaining Public Information

Certain documents that are prepared for public distribution--such as press releases, consumer publications, speeches, and congressional testimony--are available from FDA without having to file a Freedom of Information Act (FOIA) request. Many of these documents are available on FDA's Internet site (http://www.fda.gov/). We encourage you to browse the site for documents you want to look at. Public information may also be obtained by contacting the appropriate FDA information officer.

Consumers with questions about FDA-related matters also may write to the Office of Consumer Affairs, HFE-88, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or call the consumer information hot line at (1-800) 532-4440 or (301) 827-4420.

Obtaining Information Through FOIA

FOIA allows anyone to request copies of records not normally prepared for public distribution. FOIA pertains to existing records only and does not require agencies to create new records to comply with a request. It also does not require agencies to collect information they do not have or to do research or analyze data for a requestor. In addition, FOIA requests must be specific enough to permit an FDA employee who is familiar with the subject matter to locate records in a reasonable period of time.

Under FOIA, certain records may be withheld in whole or in part from the requestor if they fall within one of nine FOIA exemptions. Six of these exemptions most often form the basis for the withholding of information by the FDA:

Exemption 2: Protects certain records related solely to FDA's internal rules and practices.

Exemption 3: Protects information that is prohibited from disclosure by other laws.

Exemption 4: Protects trade secrets and confidential commercial or financial information.

Exemption 5: Protects certain interagency and intra-agency communications.

Exemption 6: Protects information about individuals in personnel, medical, and similar files when disclosure would constitute a clearly unwarranted invasion of privacy.

Exemption 7: Protects records or information compiled for law enforcement purposes when disclosure (A) could reasonably be expected to interfere with enforcement proceedings; (B) would deprive a person of a right to a fair trial or an impartial adjudication; (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy; (D) could reasonably be

expected to disclose the identity of a confidential source; (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or (F) could reasonably be expected to endanger the life or physical safety of an individual.

In the event FD elies on one or more FOIA exemptions to deny a requestor access to records, a letter stating the ons for denying the records will be sent to the requestor. The letter will also notify the reque f the right to appeal the agency's denial determination. More specific information on t emptions and on other aspects of our FOIA program are contained in FDA's FOIA implementa ulations, 21 CFR Part 20.

How to Make an FOIA Request

All FOIA requests must be in writing and should include the following information:

a. Requestor's name, address, and telephone number.

b. A description of the records being sought. The records should be identified as specifically as possible. A request for specific records that are releasable to the public can be processed much more quickly than a request for "all information" on a particular subject. Also fees for a more specific and limited request will generally be less. Information on major information systems maintained by FDA can be obtained by using the Department of Health and Human Services Government Information Locator Service (GILS) site. This information may be useful in narrowing a request.

c. Separate requests should be submitted for each firm or product involved.

d. A statement concerning willingness to pay fees, including any limitations.

All FOIA requests must be in writing. FDA does not accept FOIA requests sent via e-mail. Requests should be mailed to the following address:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

Fees

FOIA requestors may have to pay fees covering some or all of the costs of processing their request. Requestors may want to include the maximum dollar amount they are willing to pay. If the fees exceed the maximum amount stated, FDA will contact the requestor before filling the request. Requestors are generally billed for fees after their requests have been processed; however, if total fees are expected to exceed $250.00 FDA may require payment in advance of processing.

Commercial Use Requestors:

- **Search and review time:** $14, $29, or $52 per hour, depending upon the grade level of the FDA employee filling the request.
- **Duplication:** $ .10 per page for standard-size paper or actual cost per page for odd-size paper; $ .50 per fiche for microfiche.

- **Certifications:** $10 each.
- **Computer Charges:** actual cost for time involved.
- **Electronic Forms/Formats**: actual cost for form/format requested.

Noncommercial Use Requestors, Such as Representatives of the News Media, Public Interest Groups, and Educational and Noncommercial Scientific Institutions:

- Duplication charges at the same rates listed above with no charge for first 100 pages of duplication.

Other Requestors, Including Consumers:

- Search and duplication charges at rates listed above with no charge for the first two hours of search and the first 100 pages of duplication.

Requestors should not send payment with their requests. They will be billed if the total processing charges are $15 or more. FDA does not accept credit cards. Payment must be made by check or money order.

BG 97-6

FDA HOME PAGE

Page 30.3
10/7/98

National Archives and Records Administration

code of federal regulations

Select and search or browse available CFR Titles or volumes:

- All volumes for the selected Title(s) will be searched by default.
- Individual volumes can be searched by clicking the corresponding checkbox. To prevent duplicate search results, deselect the Title checkbox that the volume is in.

Maximum Records Returned: 40 Default is 40. Maximum is 200.

Search Terms:

SUBMIT | CLEAR

Search Title	*Search Volume*	*Chapter*	*Browse Parts*	*Regulatory Entity*	*O*
☑ **Title 21 Food and Drugs** **Revised April 1, 2000**	☐ 1	I	1-99	Food and Drug Administration. Department of Health and Human Services	6/2
	☐ 2		100-169		5/1
	☐ 3		170-199		6/2
	☐ 4		200-299		6/2
	☐ 5		300-499		8/1
	☐ 6		500-599		6/2

	7		600-799		7/1
	8		800-1299		7/5
	9	II	1300-1399	Drug Enforcement Administration, Department of Justice	5/2
		III	1400-1499	Office of National Drug Control Policy	

NEW CFR Titles for Sale via *GPO Access* NEW

Return to Search Terms

This document is sponsored by the Office of the Federal Register, National Archives and Records Administration on the United States Government Printing Office web site.

Questions or comments regarding this service? Contact the GPO Access User Support Team by Internet e-mail at gpoaccess@gpo.gov; by telephone at (202) 512-1530 or toll free at (888) 293-6498; by fax at (202) 512-1262.

Back GPO Home GPO INETservices

U.S. Department of Health and Human Services

Food and Drug Administration

Buying Medicines and Medical Products Online?
Click Here!

Hot Topics

LASIK Surgery

Lotronex

Accutane

Products FDA Regulates

Food
Foodborne Illness, Nutrition, Dietary Supplements...

Drugs
Prescription, Over-the-Counter, Generic...

Medical Devices
Pacemakers, Contact Lenses, Hearing Aids...

Biologics
Vaccines, Blood Products...

Animal Feed and Drugs
Livestock, Pets...

Cosmetics
Safety, Labeling...

Radiation-Emitting Products
Cell Phones, Lasers, Microwaves...

FDA NEWS

New Anti-Fungal Drug Approved. Cancidas (caspofungin acetate) is the first in a new class of anti-fungal therapies and is approved for treating aspergillosis, an infection that is potentially fatal to patients with weakened immune systems. Full Story

More FDA News
Press Releases, Meetings, Speeches...

Safety Alerts

FDA Issues Urgent Notice of Recalled Injectable Drugs

Other Recalls and Alerts

Product Approvals

Health Care Products Approved in 2000

Other Recent Approvals

FDA Activities

Advisory Committees

Clinical Trials/Human Subject Protection

Consumer Roundtable

Enforcement

FDA Modernization

Freedom of Information

International

Leveraging with FDA

MedWatch: Medical Product Reporting/Safety Information

Science @ FDA

Information For:

Consumers

Patients

Health Professionals

State/Local Officials

Industry

Press

Women

Seniors

KDS

Page 34.1
1/30/01

Science @ FDA

Let Us Hear From You	Reference Room
Report a Problem with a Product Regulated by FDA	Laws FDA Enforces
Tell Us Your Views on FDA's Proposed Regulations	Code of Federal Regulations
How to Petition FDA	Federal Register
Contact FDA	Dockets
	FDA Manuals and Publications

Subscribe to FDA's E-Mail Lists

FDA FIRSTGOV Your First Click to the U.S. Government

1-888-INFO-FDA (1-888-463-6332)
U. S. Food and Drug Administration • 5600 Fishers Lane, Rockville MD 20857-0001

FDA/Office of Public Affairs
Web page created by zwr. Last updated by clb Jan. 29, 2001

Page 34.2
1/30/01

Office of Regulatory Affairs
Imports

ORA Import Program

ORA Site QuickNav

- Imports
- Inspections
- Science
- Compliance
- Federal-State Partnership
- Consumer
- Industry
- Recall
- Reinvention
- Field Contacts
- EFOI Reading Room

Welcome to FDA's Import Program

Information related to products subject to FDA's control of foods (except for certain meats and poultry products), drugs (human, animal and biological), cosmetics, medical devices and radiation emitting devices, etc., offered for entry into the United States through U.S. Customs , in support of FDA's regulatory activities.

Overview of Import Program FDA's import program is designed to enforce the Federal Food, Drug, and Cosmetic Act and other related Acts (Federal laws) to protect consumers' health and safety, and from economic fraud.

Using FDAs, Automated Import System (OASIS). This link offers access to the **OASIS** Information Sections . These pages contain guidance and information about the **OASIS SYSTEM** (**O**perational and **A**dministration **S**ystem for **I**mport **S**upport)

Current Import Alerts

FDA's Import Alerts provides guidance to district offices concerning unusual or new problems affecting imported products or provides guidance for detention without physical examination of products which appear to be in violation of the law.

Access to Import Detention Report

Monthly detention reports of imported products which appear violative under the laws enforced by FDA.

Access to Import for Export

FDA's guidance to field offices regarding the procedures to be used for evaluating importation of violative articles (including drug and device components, food and color additives, and dietary supplements) intended for further processing and export.

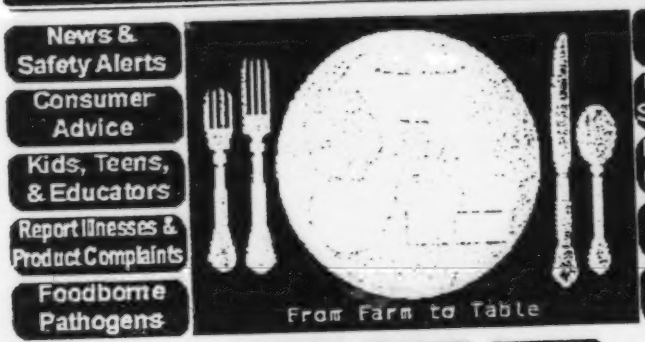
Download a tool to determine FDA Product Codes FDA Product Code Builder

access to **OASIS home page**

Page 34.3
1/30/01

www.FoodSafety.gov

Gateway to Government Food Safety Information



News & Safety Alerts | Consumer Advice | Kids, Teens, & Educators | Report Illnesses & Product Complaints | Foodborne Pathogens

Industry Assistance | National Food Safety Initiative | Federal & State Gov't Agencies | Other Topics | Search & Site Index

Videos | FAQs | Languages

Selected Highlights

- Food Safety Strategic Plan
- *Listeria monocytogenes* Announcements
- *Vibrio parahaemolyticus* Announcements
- Juice HACCP Announcements
- Import Safety Announcements
- The FDA, Food Allergens, and You
- Food Safety Tool for Science Teachers (FSIS)
- For Physicians: A Foodborne Illness Primer(FSIS)
- Food Safety Grand Rounds live satellite broadcast and web cast (January 26, 2001, 2:00 - 3:00pm)
- Food Safety News from CDC | EPA | FSIS | FDA

- Recent Additions to the FoodSafety.gov web site

- President's Council on Food Safety
- Partnership for Food Safety Education (Fight BAC!)
- Food Safety Training and Education Alliance
- International

www.FoodSafety.gov
Gateway to Government Food Safety Information

Industry Assistance

News & Safety Alerts
Consumer Advice
Kids, Teens, & Educators
Industry Assistance
Report Illnesses & Product Complaints
Foodborne Pathogens
National Food Safety Initiative
Federal & State Gov't Agencies
Other Topics
Search & Site Index

General Industry Assistance

- Information Materials for the Food and Cosmetics Industries (FDA)
- Domestic/Import Food Industry Questions & Answers (FDA)

HACCP

- Hazard Analysis and Critical Control Point (HACCP)

Imports

- Importing Food

Retail & Food Service

- Nursing Homes/Hospitals, Schools, Day Cares, Groceries, Restaurants,etc.

Pesticides and Other Chemical Contaminants

- Pesticides, Antimicrobials, Heavy Metals, & Chemical Contaminants

Produce

- Guide at a Glance (FDA)

Eggs

- FDA Finalizes Safe Handling Labels and Refrigeration Requirements for Marketing Shell Eggs - November 30, 2000 (FDA)
- Food Service Safety Facts (FDA)
- Enforcement of Refrigeration and Labeling Requirements for Shell Eggs Packed for Consumer Use (FSIS)

Advertising

Page 34.5
1/30/01

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

Acidified and Low-Acid Canned Foods

Regulations | Registration and Process Filing Forms
Inspectional Forms and Guides | Import Detentions & Import Guides
Non-Government Sources

Regulations

- FDA Requirements for Establishment Registration, Thermal Process Filing, and Good Manufacturing Practices for Low-Acid Canned Foods and Acidified Foods
  - Overview
  - 21 CFR
    - 21 CFR 108 (TEXT PDF*)
    - 21 CFR 110 (TEXT PDF*)
    - 21 CFR 113 (TEXT PDF*)
    - 21 CFR 114 (TEXT PDF*)

Registration, Process Filing Forms, Instructions and Guidelines

- Low Acid Canned Food Process Filing Improvement Underway
- Instructions for Establishment Registration and Process Filing Forms
  - Food Canning Establishment Registration FDA 2541 (PDF) *
  - Process Food Canning Establishment Filing for All Methods Except Low Acid Aseptic FDA 2541a (PDF) *
  - Process Food Canning Establishment Filing for Low-Acid Aseptic Process FDA 2541c (PDF)*

Inspectional Forms and Guides

- FDA Inspectional References (Manuals and other documents that provide procedures and guidance to FDA personnel for conducting their inspectional and investigational activities).

- **Low-Acid Canned Food Manufacturer's Guides**
  - Low-Acid Canned Food Manufacturers Part 1: Administrative Procedures / Scheduled Processes
  - Low-Acid Canned Food Manufacturers Part 2: Processes-Procedures
  - Acidified Food Manufacturers
  - Approximate pH of Foods and Food Products NEW

- Form FDA 3146: Domestic Acidified and Low-Acid Canned Foods Inspection Report (PDF)*

- Form FDA 3146a: Domestic Low Acid Canned Foods Retort Data Sheet (Processing in Steam in Still Reports (PDF)*

Import Detentions & Import Guides

- FDA Import Procedures
- FDA Importer's Guide
- Import Alerts
  - Introduction
  - Import Alerts by Number
  - Import Alert 99-04 Detention without Physical Exam of Manufacturers of Low-Acid Canned Food and Acidified Foods (Revised July 14, 1999)

Information from Non-Government Sources

- Institute for Thermal Processing Specialists
  - Protocols

*PDF Readers are available for free from the Adobe Acrobat web site.

Hypertext updated by dms/ear 2000-SEP-26

Page 35.2
1/30/01

U.S. Food and Drug Administration

Information for Companies Regulated by FDA

On This Page:

General Information

Small Business

Product-Specific Information

Other News Sources:

FDA News

Media Contacts and Public Affairs

Product Approvals

Get FDA News by E-Mail

General Information

Code of Federal Regulations Title 21

Federal Register Documents Published by FDA

Dockets

Freedom of Information

Laws Enforced by FDA

Office of Regulatory Affairs Industry Assistance

Ombudsman

FDA Field Offices

Publications, Manuals, References

State Contract Information (Office of Regulatory Affairs)

U.S. Business Advisor

Warning Letters

Small Business

Regional Small Business Representatives

Small Business Contacts in FDA Centers

Small Business Program Office

Product-Specific Information

Biologics

Page 36.1
1/30/01

Cosmetics

Drugs

Food

- Inspections, Compliance, Enforcements and Recalls
- Industry Assistance
- Starting a Food Business

Medical Devices

FDA/Website Management Staff
Web page created by clb 2000-OCT-31.
Last updated by tg 2000-DEC-08.

Page 36.2
1/30/01

Importation of Animal Products

Animal feeds, pet food, color and food additives, drugs, and devices, intended for animals are generally subject to the same requirements of the Federal Food, Drug, and Cosmetic Act (Act) as similar products for human use. However, there are some important differences. For example, use of new animal drugs in the manufacture of animal feeds requires approval of an application; animal biologics are subject to the Virus, Serun, and Toxin Act administered by the U.S. Department of Agriculture; medical devices for animals are not subject to premarket approval; and, cosmetics for animals (grooming aids) are not subject to the Act, provided no therapeutic claims are made.

Animal Feeds and Pet Foods: In addition to meeting the requirements of the Act, both commercial feeds and pet food must meet the requirements of individual state laws. Pet foods are also subject to the labeling requirements of the Fair Packaging and Labeling Act (FPLA). All medicated feeds containing drugs must, whether bagged or in bulk, be adequately labeled, bearing all mandatory labeling information. As with human food, animal feeds and pet food may not be adulterated or misbranded and canned pet food must be manufactured and registered in accordance with the low-acid canned food (LACF) regulations.

Food Additives: Substances that, because of their intended use, may become conponents of animal feed or pet food, either directly or indirectly, or that may otherwise affect the characteristics of the animal feed or pet food, are "food additives." Food additives are subject to prior approval or regulation for their safe use.

Medicated Feeds: Medicated feeds and medicated feed premixes ("type A articles") must be manufactured, processed, packaged, or held under methods, facilities, and controls that conform to the requirements of current Good Manufacturing Practices (GMPs) regulations. Manufacturers if animal feeds which contain new animal drugs must submit a Medicated Feed Application form FDA-1900, unless a waiver has been granted by regulation. Manufacturers of medicated feed prenixes and certain medicated feeds must register annually. Medicated feed prenixes, domestic or imported, must be listed, whereas, medicated feeds are not required to be listed.

Animal Grooming Aids (Cosmetics): Products intended for cleansing or promoting attractiveness of animals are not subject to FDA control. However, if such products are represented for any therapeutic purpose or as containing an active drug ingredient, they would be subject to the Act as an animal drug, or possibly, as an animal device.

Animal Devices: There are no requirements for FDA approval of devices not intended for human use. Nor are there listing or registration requirements. However, animal device labeling may not be false or misleading, nor may the product be otherwise misbranded or adulterated. The device must be safe and effective for its intended use. Animal prescription devices may be dispensed only by a U.S. licensed veterinarian or on the prescription of a licensed veterinarian, and the device's labeling must bear the Rx (prescription) legend.